

PSJ17 Exh 33

**CORPORATE INTEGRITY AGREEMENT
BETWEEN THE
OFFICE OF INSPECTOR GENERAL
OF THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES
AND
CEPHALON, INC.**

I. PREAMBLE

Cephalon, Inc. (Cephalon) hereby enters into this Corporate Integrity Agreement (CIA) with the Office of Inspector General (OIG) of the United States Department of Health and Human Services (HHS) to promote compliance with the statutes, regulations, and written directives of Medicare, Medicaid, and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) (Federal health care program requirements) and with the statutes, regulations, and written directives of the Food and Drug Administration (FDA requirements). Contemporaneously with this CIA, Cephalon is entering into a Settlement Agreement with the United States. Cephalon will also enter into settlement agreements with various States (Related State Settlement Agreements) and Cephalon's agreement to this CIA is a condition precedent to those agreements.

Prior to the Effective Date of this CIA (as defined below), Cephalon established a voluntary compliance program (known as "Global Compliance" or "Global Compliance Program") applicable to all Cephalon employees including employees in Worldwide Pharmaceutical Operations. Cephalon's Global Compliance Program includes an Executive Vice President, Chief Compliance Officer who reports directly to the Audit Committee of the Board of Directors and to the CEO, and a Compliance Committee. The Global Compliance Program also includes a Code of Conduct applicable to all employees that is regularly reviewed and disseminated, written policies and procedures that, as represented by Cephalon, promote high ethical standards, educational and training initiatives that, as represented by Cephalon, help to ensure compliance with applicable laws and regulations, a Disclosure Program that allows for the confidential disclosure and investigation of potential compliance violations and appropriate disciplinary procedures, screening measures for Ineligible Persons, and regular internal auditing procedures.

Cephalon shall continue its Compliance Program throughout the term of this CIA and shall do so in accordance with the terms set forth below. Cephalon may modify its

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Compliance Program as appropriate, but, at a minimum, Cephalon shall ensure that during the term of this CIA, it shall comply with the obligations set forth herein.

II. TERM AND SCOPE OF THE CIA

A. The period of the compliance obligations assumed by Cephalon under this CIA shall be five years from the effective date of this CIA, unless otherwise specified. The effective date shall be the date on which the final signatory of this CIA executes this CIA (Effective Date). Each one-year period, beginning with the one-year period following the first day of the first calendar month following the Effective Date, shall be referred to as a "Reporting Period."

B. Sections VII, IX, X, and XI shall expire no later than 120 days after OIG's receipt of: (1) Cephalon's final Annual Report; or (2) any additional materials submitted by Cephalon pursuant to OIG's request, whichever is later.

C. The scope of this CIA shall be governed by the following definitions:

1. "Covered Persons" includes:

a. all owners who are natural persons (other than shareholders who: (1) have an ownership interest of less than 5%; and (2) acquired the ownership interest through public trading), officers, directors, and United States-based employees of Cephalon; and

b. all contractors, subcontractors, agents, and other persons who perform Promotional and Product Services Related Functions (as defined below in Section II.C.4) on behalf of Cephalon.

Notwithstanding the above, this term does not include part-time or per diem employees, contractors, subcontractors, agents, and other persons who are not reasonably expected to work more than 160 hours per year, except that any such individuals shall become "Covered Persons" at the point when they work more than 160 hours during the calendar year.

2. "Relevant Covered Persons" includes all Covered Persons whose job responsibilities relate to Promotional and Product Services Related Functions.
3. "Government Reimbursed Products" refers to all Cephalon products that are reimbursed by Federal health care programs. This term includes products that are promoted by Cephalon for which it may not hold the New Drug Application.
4. The term "Promotional and Product Services Related Functions" includes: (a) the promotion, marketing, and sale of Government Reimbursed Products; and (b) the development or dissemination of materials or information about, or the provision of services relating to, Government Reimbursed Products.
5. The term "Third Party Educational Activity" shall mean any continuing medical education (CME), independent medical education (IME), disease awareness, or other scientific, educational, or professional program, meeting, or event sponsored by Cephalon, including but not limited to, sponsorship of symposia at medical conferences.
6. The term "Third Party Personnel" shall mean personnel of the entities with whom Cephalon has or may in the future enter into agreements to co-promote a Government Reimbursed Product in the United States or engage in joint promotional activities in the United States relating to such a product. Cephalon has represented that: (1) the Third Party Personnel are employed by other independent entities; (2) Cephalon does not control Third Party Personnel; and (3) it would be commercially impracticable to compel the compliance of Third Party Personnel with the requirements set forth in this CIA. Cephalon agrees to promote compliance by Third Party Personnel with Federal health care program and FDA requirements by complying with the provisions set forth below in Sections III.B.2, V.A.3, and V.B.4 related to Third Party Personnel who meet the definition of Covered Persons. Provided that Cephalon complies with the requirements of Sections III.B.2, V.A.3, and V.B.4, Cephalon shall not be required to fulfill the other CIA

obligations that would otherwise apply to Third Party Personnel who meet the definition of Covered Persons.

III. CORPORATE INTEGRITY OBLIGATIONS

Cephalon shall establish and maintain a Compliance Program throughout the term of this CIA that includes the following elements:

A. Compliance Responsibilities of Chief Compliance Officer, Compliance Committee, the Board of Directors, and Management Certifications.

1. *Chief Compliance Officer.* Prior to the Effective Date, Cephalon appointed a Chief Compliance Officer, and Cephalon shall maintain a Chief Compliance Officer during the term of the CIA. The Chief Compliance Officer shall be responsible for developing and implementing policies, procedures, and practices designed to ensure compliance with the requirements set forth in this CIA and with Federal health care program requirements and FDA requirements. The Chief Compliance Officer is and shall continue to be a member of executive management of Cephalon, shall make periodic (at least quarterly) reports regarding compliance matters directly to the Audit Committee of the Board of Directors of Cephalon, and shall be authorized to report on such matters to the Board of Directors at any time. The Chief Compliance Officer shall not be or be subordinate to the General Counsel or Chief Financial Officer. The Chief Compliance Officer shall be responsible for monitoring the day-to-day compliance activities engaged in by Cephalon as well as for any reporting obligations created under this CIA.

Cephalon shall report to OIG, in writing, any changes in the identity or position description of the Chief Compliance Officer, or any actions or changes that would affect the Chief Compliance Officer's ability to perform the duties necessary to meet the obligations in this CIA, within 15 days after such a change.

2. *Compliance Committee.* Prior to the Effective Date, Cephalon established a Compliance Committee, and Cephalon shall maintain a Compliance Committee during the term of this CIA. The Compliance Committee shall, at a minimum, include the Chief Compliance Officer and other members of senior management necessary to meet the requirements of this CIA (e.g., senior managers of relevant departments, such as legal, medical affairs, sales, marketing, human resources, and internal audit). The Chief Compliance Officer shall chair the Compliance Committee and the Committee shall support the Chief Compliance Officer in fulfilling his/her

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responsibilities (e.g., shall assist in the analysis of the organization's risk areas and shall receive reports on compliance-related monitoring, audits, and investigations).

Cephalon shall report to OIG, in writing, any changes in the composition of the Compliance Committee, or any actions or changes that would affect the Compliance Committee's ability to perform the duties necessary to meet the obligations in this CIA, within 15 days after such a change.

3. *Board of Directors.* The Board of Directors (Board) or a Committee of the Board, if applicable, shall be responsible for the review and oversight of matters related to compliance with Federal health care program requirements, FDA requirements, and the obligations of this CIA. The Board, or a Committee of the Board, shall, at a minimum, be responsible for the following:

a. meeting at least quarterly to review and oversee Cephalon's Global Compliance Program, including but not limited to the performance of the Chief Compliance Officer and Global Compliance department.

b. for each Reporting Period of the CIA, adopting a resolution (pursuant to the process outlined in the bylaws for adopting resolutions) summarizing its review and oversight of Cephalon's compliance with Federal health care program requirements, FDA requirements, and the obligations of this CIA. Each individual member of the Board or, if applicable, each member of the Committee of the Board having responsibility for compliance, shall sign a statement indicating that he or she agrees with the resolution.

At minimum, the resolution shall include the following language:

"The Board of Directors [or a Committee of the Board] has made a reasonable inquiry into the operations of Cephalon's Global Compliance Program, including the performance of the Chief Compliance Officer and the Global Compliance department. Based on its inquiry, the Board [or Committee] has concluded that, to the best of its knowledge, Cephalon has implemented an effective Global Compliance Program to meet the Federal health care program requirements, FDA requirements, and the obligations of the CIA."

If the Board (or the Board Committee) is unable to provide such a conclusion in the resolution, the Board (or Committee) shall include in the resolution a written explanation of the reasons why it is unable to provide the conclusion and the steps it is taking to implement an effective Compliance Program at Cephalon.

Cephalon shall report to OIG, in writing, any changes in the composition of the Board, or any actions or changes that would affect the Board's ability to perform the duties necessary to meet the obligations in this CIA, within 15 days after such a change.

4. *Management Accountability and Certifications:* Cephalon represents that compliance is a component of each employee's performance objectives. In addition to the responsibilities set forth in this CIA for all Covered Persons, certain Cephalon employees ("Certifying Employees") are specifically expected to monitor and oversee activities within their areas of authority and shall annually certify in writing or electronically that the applicable area of authority is compliant with Federal health care program requirements, FDA requirements, and the obligations of this CIA. The Certifying Employees include, at a minimum, the following: Chairman and Chief Executive Officer, Executive Vice President of Worldwide Medical and Regulatory Operations, Executive Vice President of Worldwide Pharmaceutical Operations, all business unit sales vice presidents, all business unit marketing vice presidents, all business unit sales directors, all business unit marketing directors, the Vice President of Worldwide Medical Affairs, and all medical directors of communications and medical science liaisons (MSLs).

For each Reporting Period, each Certifying Employee shall certify in writing or electronically that:

"I have been trained on and understand the compliance requirements and responsibilities as they relate to [department or functional area], an area under my supervision. My job responsibilities include ensuring compliance with regard to the _____ [insert name of the department or functional area.] To the best of my knowledge, except as otherwise described herein, the _____ [insert name of department or functional area] of Cephalon is in compliance with all applicable Federal health care program requirements, FDA requirements, and the obligations of the CIA."

B. Written Standards.

1. *Code of Conduct.* Prior to the Effective Date, Cephalon developed, implemented, and distributed a written Code of Conduct to all Covered Persons. Cephalon currently requires all newly employed persons to certify in writing or electronically that they have received, read, understood, and shall abide by Cephalon's Code of Conduct. Cephalon shall continue to make the promotion of, and adherence to, the Code of Conduct an element in evaluating the performance of all employees.

The Code of Conduct sets forth and shall continue to set forth, at a minimum, the following:

- a. Cephalon's commitment to full compliance with all Federal health care program and FDA requirements, including its commitment to market, sell, promote, research, develop, provide information about, and advertise its products in accordance with Federal health program requirements and FDA requirements;
- b. Cephalon's requirement that all of its Covered Persons shall be expected to comply with all Federal health care program and FDA requirements and with Cephalon's own Policies and Procedures as implemented pursuant to Section III.B (including the requirements of this CIA);
- c. the requirement that all of Cephalon's Covered Persons shall be expected to report to the Chief Compliance Officer, or other appropriate individual designated by Cephalon, suspected violations of any Federal health care program and FDA requirements or of Cephalon's own Policies and Procedures;
- d. the possible consequences to both Cephalon and Covered Persons of failure to comply with Federal health care program and FDA requirements and with Cephalon's own Policies and Procedures and the failure to report such noncompliance; and
- e. the right of all individuals to use the Disclosure Program described in Section III.E, and Cephalon's commitment to nonretaliation and to

maintain, as appropriate, confidentiality and anonymity with respect to such disclosures.

To the extent not already accomplished, within 120 days after the Effective Date, the Code of Conduct shall be distributed to each Covered Person and each Covered Person shall certify, in writing or electronically, that he or she has received, read, understood, and shall abide by Cephalon's Code of Conduct. New Covered Persons shall receive the Code of Conduct and shall complete the required certification within 30 days after becoming a Covered Person or within 120 days after the Effective Date, whichever is later.

Cephalon shall periodically review the Code of Conduct to determine if revisions are appropriate and shall make any necessary revisions based on such review. Any revised Code of Conduct shall be distributed within 30 days after any revisions are finalized. Each Covered Person shall certify, in writing or electronically, that he or she has received, read, understood, and shall abide by the revised Code of Conduct within 30 days after the distribution of the revised Code of Conduct.

2. *Third Party Personnel.* Within 90 days after the Effective Date, and annually thereafter by the anniversary of the Effective Date, Cephalon shall send a letter to each entity employing Third Party Personnel. The letter shall outline Cephalon's obligations under the CIA and its commitment to full compliance with all Federal health care program and FDA requirements. The letter shall include a description of Cephalon's Compliance Program. Cephalon shall attach a copy of its Code of Conduct to the letter and shall request the entity employing Third Party Personnel to either: (a) make a copy of Cephalon's Code of Conduct and a description of Cephalon's Compliance Program available to its Third Party Personnel; or (b) represent to Cephalon that it has and enforces a substantially comparable code of conduct and compliance program for its Third Party Personnel.

3. *Policies and Procedures.* Prior to the Effective Date, Cephalon implemented written Policies and Procedures regarding the operation of the Compliance Program and Cephalon's compliance with Federal health care program and FDA requirements (Policies and Procedures). To the extent not already accomplished, within 120 days after the Effective Date, Cephalon shall ensure that the Policies and Procedures address or shall continue to address:

- a. the subjects relating to the Code of Conduct identified in Section III.B.1;
- b. appropriate ways to conduct Promotional and Product Services Related Functions in compliance with all applicable Federal healthcare program requirements, including, but not limited to the Federal anti-kickback statute (codified at 42 U.S.C. § 1320a-7b), and the False Claims Act (codified at 31 U.S.C. §§ 3729-3733);
- c. appropriate ways to conduct Promotional and Product Services Related Functions in compliance with all applicable FDA requirements;
- d. the mechanisms through, and manner in which, Cephalon receives and responds to requests for information about non-FDA approved (or "off-label") uses of Cephalon's products; the form and content of information disseminated by Cephalon in response to such requests; and the internal review process for the information disseminated.

The Policies and Procedures shall include a requirement that Cephalon develop a database to track requests for information about Cephalon's products that are made to Cephalon's Medical Services (MS) department. This database shall be referred to as the "Inquiries Database." The Inquiries Database shall include the following items of information for each unique inquiry (Inquiry) received for information about Cephalon's products: 1) date of Inquiry; 2) form of Inquiry (e.g., fax, phone, etc.); 3) name of the requesting health care professional (HCP) or health care institution (HCI); 4) nature and topic of request (including exact language of the Inquiry if made in writing); 5) nature/form of the response from Cephalon (including a record of the materials provided to the HCP or HCI in response to the request); and 6) the name of the Cephalon representative who called on or interacted with the HCP or HCI. Any response from Medical Services to an HCP or HCI shall identify whether the information provided addresses an indication that is part of the approved

product label. The status and findings of any follow-up review conducted by Cephalon in situations in which it appears that the Inquiry may have related to improper off-label promotion shall be maintained by Global Compliance and the information shall be included in the Inquiry Reports further discussed in Section III.A.2 of Appendix B;

- e. development of call plans for field sales representatives who promote Government Reimbursed Products. For each product, the Policies and Procedures shall require that Cephalon review the call plans for the product and the bases upon which specified physician specialties and institutional provider types are included in, or excluded from, the call plans. The Policies and Procedures shall also require that Cephalon modify the call plans as necessary to ensure that Cephalon is promoting its products in a manner that complies with all applicable Federal health care program and FDA requirements. The call plan reviews shall occur at least annually and shall also occur each time the FDA approves a new or additional indication for a Government Reimbursed Product;
- f. consultant or other fee-for-service arrangements entered into with HCPs or HCIs (including, but not limited to, speaker programs, speaker training programs, advisory boards, or any other financial relationship with an HCP or HCI) and all events and expenses relating to such engagements or arrangements. These Policies and Procedures shall be designed to ensure that the arrangements and related events are used for legitimate and lawful purposes in accordance with applicable Federal health care program and FDA requirements. The Policies and Procedures shall include requirements about the content and circumstances of such arrangements and events;
- g. programs to educate field representatives, including preceptorships. These Policies and Procedures shall be designed to ensure that the programs are used for legitimate and lawful purposes in accordance with applicable Federal health care

program and FDA requirements. The Policies shall include requirements about the content and circumstances of such arrangements and events;

- h. sponsorship or funding of grants (including educational grants) or charitable contributions. These Policies and Procedures shall be designed to ensure that Cephalon's funding and/or sponsorship complies with all applicable Federal health care program and FDA requirements;
- i. funding of, or participation in, any Third Party Educational Activity. These Policies and Procedures shall be designed to ensure that Cephalon's funding and/or sponsorship of such programs satisfies all applicable Federal health care program and FDA requirements.

The Policies and Procedures shall require that: 1) Cephalon disclose its financial support of the Third Party Educational Activity and any financial relationships with faculty, speakers, or organizers at such Activity; 2) as a condition of funding, the third party shall agree to disclose Cephalon's financial support of the Third Party Educational Activity and any financial relationships that Cephalon might have with faculty, speakers, or organizers at such Activity; 3) any faculty, speakers, or organizers at the Third Party Educational Activity disclose any financial relationship with Cephalon; 4) the Third Party Educational Activity have an educational focus; 5) the content, organization, and operation of the Third Party Educational Activity be independent of Cephalon control; 6) Cephalon support only Third Party Educational Activity that is non-promotional in tone/nature; and 7) Cephalon's support of a Third Party Educational Activity shall be contingent on the provider's commitment to provide information at the Educational Activity that is fair, balanced, accurate and not misleading;

- j. review of promotional materials by appropriate qualified personnel (such as regulatory, medical, and/or legal personnel),

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and the review of other materials and information intended to be disseminated outside Cephalon in a manner designed to ensure that legal, regulatory, and medical concerns are properly addressed during Cephalon's review and approval process and are elevated when appropriate. The Policies and Procedures shall be designed to ensure that such materials and information, when finally approved, comply with all applicable Federal health care program and FDA requirements;

- k. sponsorship or funding of research or related activities. These Policies and Procedures shall be designed to ensure that Cephalon's funding and/or sponsorship complies with all applicable Federal health care program and FDA requirements;
- l. compensation (including salaries and bonuses) for Relevant Covered Persons. These Policies and Procedures shall be designed to ensure that financial incentives do not inappropriately motivate such individuals to engage in improper promotion, sales, and marketing of Cephalon's products;
- m. disciplinary policies and procedures for violations of Cephalon's Policies and Procedures, including policies relating to Federal health care program and FDA requirements.

To the extent not already accomplished, within 120 days after the Effective Date, the relevant portions of the Policies and Procedures shall be made available to all individuals whose job functions relate to those Policies and Procedures. Appropriate and knowledgeable staff shall be available to explain the Policies and Procedures.

At least annually (and more frequently, if appropriate), Cephalon shall assess and update, as necessary, the Policies and Procedures. Within 30 days after the effective date of any revisions, the relevant portions of any such revised Policies and Procedures shall be made available to all individuals whose job functions relate to those Policies and Procedures.

C. Training and Education.

Cephalon represents that it provides training to its employees on a regular basis concerning a variety of topics. The training required by this CIA need not be separate and distinct from the regular training provided by Cephalon, but instead may be integrated fully into such regular training so long as the training covers the areas specified below.

1. *General Training.* Within 120 days after the Effective Date, Cephalon shall provide at least two hours of General Training to each Covered Person. This training, at a minimum, shall explain Cephalon's:

- a. CIA requirements; and
- b. Cephalon's Compliance Program (including the Code of Conduct and the Policies and Procedures as they pertain to general compliance issues).

To the extent that Cephalon provided General Training to Covered Persons during the 180 days immediately prior to the Effective Date that satisfied the requirements set forth in Section III.C.1.b above, the OIG shall credit that training for purposes of satisfying Cephalon's General Training obligations of Section III.C.1 for the first Reporting Period. Cephalon may satisfy its remaining General Training obligations for the Covered Persons who received the training described in the preceding sentence by notifying them within 90 days after the Effective Date in writing or in electronic format of the fact that Cephalon entered a CIA and providing an explanation of Cephalon's requirements and obligations under the CIA.

New Covered Persons shall receive the General Training described above within 30 days after becoming a Covered Person or within 120 days after the Effective Date, whichever is later. After receiving the initial General Training described above, each Covered Person shall receive at least one hour of General Training in each subsequent Reporting Period.

2. *Specific Training.* Within 120 days after the Effective Date, each Relevant Covered Person shall receive at least three hours of Specific Training in addition to the General Training required above.

This Specific Training shall include a discussion of:

- a. all applicable Federal health care program requirements relating to Promotional and Product Services Related Functions;
- b. all applicable FDA requirements relating to Promotional and Product Services Related Functions;
- c. all Cephalon policies, procedures, and other requirements applicable to Promotional and Product Services Related Functions;
- d. the personal obligation of each individual involved in Promotional and Product Services Related Functions to comply with all applicable Federal health care program and FDA requirements and all other applicable legal requirements;
- e. the legal sanctions for violations of the applicable Federal health care program and FDA requirements; and
- f. **examples of proper and improper practices related to Promotional and Product Services Related Functions.**

To the extent that Cephalon provided Specific Training to Relevant Covered Persons during the 180 days immediately prior to the Effective Date that satisfied the requirements set forth in Section III.C.2 above, the OIG shall credit that training for purposes of satisfying Cephalon's Specific Training obligations of this Section III.C.2 for the first Reporting Period.

New Relevant Covered Persons shall receive this training within 30 days after the beginning of their employment or becoming Relevant Covered Persons, or within 120 days after the Effective Date, whichever is later. A Cephalon employee who has completed the Specific Training shall review a new Relevant Covered Person's work, to the extent that the work relates to Promotional and Product Services Related Functions, until such time as the new Relevant Covered Person completes his or her Specific Training.

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After receiving the initial Specific Training described in this Section, each Relevant Covered Person shall receive at least two hours of Specific Training in each subsequent Reporting Period.

3. *Certification.* Each individual who is required to attend training shall certify, in writing or electronically, that he or she has received the required training. The certification shall specify the type of training received and the date received. The Compliance Officer (or designee) shall retain the certifications, along with all course materials. These shall be made available to OIG, upon request.

4. *Qualifications of Trainer.* Persons providing the training shall be knowledgeable about the subject area of the training, including applicable Federal health care program and FDA requirements. The training and education required under this Section III.C may be provided by supervisory employees, knowledgeable staff, Cephalon trainers, and/or outside consultant trainers selected by Cephalon or may be satisfied by relevant, accredited continuing education programs provided they cover topics outlined above in Section III.C.2.

5. *Update of Training.* Cephalon shall review the training annually, and, where appropriate, update the training to reflect changes in Federal health care program requirements, FDA requirements, any issues discovered during any internal audits or any IRO Review, and any other relevant information.

6. *Computer-based Training.* Cephalon may provide the training required under this CIA through appropriate computer-based training approaches. If Cephalon chooses to provide computer-based training, it shall make available appropriately qualified and knowledgeable staff or trainers to answer questions or provide additional information to the individuals receiving such training. In addition, if Cephalon chooses to provide computer-based General or Specific Training, all applicable requirements to provide a number of "hours" of training in this Section III.C may be met with respect to computer-based training by providing the required number of "normative" hours as that term is used in the computer-based training industry.

D. Review Procedures.

1. *General Description.*

a. *Engagement of Independent Review Organization.* Within 90 days after the Effective Date, Cephalon shall engage an entity (or entities), such as an accounting, auditing, or consulting firm (hereinafter "Independent Review Organization" or "IRO"), to perform reviews to assist Cephalon in assessing and evaluating its Promotional and Product Services Related Functions. The applicable requirements relating to the IRO are outlined in Appendix A to this CIA, which is incorporated by reference.

Each IRO engaged by Cephalon shall have expertise in applicable Federal health care program and FDA requirements as may be appropriate to the Review for which the IRO is retained. Each IRO shall assess, along with Cephalon, whether it can perform the engagement in a professionally independent and objective fashion, as appropriate to the nature of the review, taking into account any other business relationships or other engagements that may exist.

The IRO(s) shall conduct reviews that assess Cephalon's systems, processes, policies, procedures, and practices relating to Promotional and Product Services Related Functions (Promotional and Product Services Reviews).

b. *Frequency and Brief Description of Reviews.* As set forth more fully in Appendix B, the Promotional and Product Services Review shall consist of two components - a Systems Review and a Transactions Review. The Systems Review shall assess Cephalon's systems, processes, policies, and procedures relating to Promotional and Product Services Related Functions. If there are no material changes in Cephalon's systems, processes, policies, and procedures relating to Promotional and Product Services Related Functions, the Promotional and Product Services Systems Review shall be performed for the periods covering the first and fourth Reporting Periods. If Cephalon materially changes its systems, processes,

policies, and procedures relating to Promotional and Product Services Related Functions, the IRO shall perform a Systems Review for the Reporting Period in which such changes were made in addition to conducting the Systems Review for the first and fourth Reporting Periods.

The Promotional and Product Services Transactions Review shall be performed annually and shall cover each of the five Reporting Periods. The IRO(s) shall perform all components of each annual Transaction Review. As set forth more fully in Appendix B, the Transactions Review shall include several components, including a review relating to Inquiries included in Cephalon's Inquiries Database, a review of Cephalon's Call Plan Assessments, and a review of a records relating to a sample of the Payments that are reported by Cephalon pursuant to Section III.M below. In addition, beginning with the second Reporting Period, each Transactions Review shall also include a review of up to three additional areas or practices of Cephalon identified by the OIG in its discretion (hereafter "Additional Items").

For purposes of identifying the Additional Items to be included in the Transactions Review for a particular Reporting Period, the OIG will consult with Cephalon and may consider internal audit work conducted or planned by Cephalon, Cephalon's product portfolio, the nature and scope of Cephalon's promotional practices and arrangements with HCPs, and other information known to it. As set forth more fully in Section III.D of Appendix B, Cephalon may propose to the OIG that its internal audit(s) be partially substituted for one or more of the Additional Items that would otherwise be reviewed by the IRO as part of the Transactions Review. The OIG retains sole discretion over whether, and in what manner, to allow Cephalon's internal audit work to be substituted for a portion of the Additional Items review conducted by the IRO.

The OIG shall notify Cephalon of the nature and scope of the IRO review for each of the Additional Items no later than 90 days prior to the end of the second through fifth Reporting Periods. Prior to

undertaking the review of the Additional Items, the IRO and/or Cephalon shall submit an audit work plan to the OIG for approval and the IRO shall conduct the review of the Additional Items based on a work plan approved by the OIG.

c. *Retention of Records.* The IRO and Cephalon shall retain and make available to OIG, upon request, all work papers, supporting documentation, correspondence, and draft reports (those exchanged between the IRO and Cephalon) related to the reviews.

2. *IRO Review Reports.* The IRO(s) shall prepare a report (or reports) based upon each Review performed. The information and content to be included in the report is described in Appendix B, which is incorporated by reference.

3. *Validation Review.* In the event OIG has reason to believe that: (a) any IRO Review fails to conform to the requirements of this CIA; or (b) the IRO's findings or Review results are inaccurate, OIG may, at its sole discretion, conduct its own review to determine whether the applicable IRO Review complied with the requirements of the CIA and/or the findings or Review results are inaccurate (Validation Review). Cephalon shall pay for the reasonable cost of any such review performed by OIG or any of its designated agents. Any Validation Review of Reports submitted as part of Cephalon's final Annual Report shall be initiated no later than one year after Cephalon's final submission (as described in Section II) is received by OIG.

Prior to initiating a Validation Review, OIG shall notify Cephalon of its intent to do so and provide a written explanation of why OIG believes such a review is necessary. To resolve any concerns raised by OIG, Cephalon may request a meeting with OIG to: (a) discuss the results of any Review submissions or findings; (b) present any additional information to clarify the results of the applicable Review or to correct the inaccuracy of the Review; and/or (c) propose alternatives to the proposed Validation Review. Cephalon agrees to provide any additional information as may be requested by OIG under this Section III.D.3 in an expedited manner. OIG will attempt in good faith to resolve any Review issues with Cephalon prior to conducting a Validation Review. However, the final determination as to whether or not to proceed with a Validation Review shall be made at the sole discretion of OIG.

4. *Independence and Objectivity Certification.* The IRO shall include in its report(s) to Cephalon a certification or sworn affidavit that it has evaluated its professional independence and objectivity, as appropriate to the nature of the engagement, with regard to the applicable Review and that it has concluded that it is, in fact, independent and objective.

E. Disclosure Program.

Cephalon represents that it has a disclosure program designed to facilitate communications relating to compliance with Federal health care program and FDA requirements and Cephalon's policies (the "Disclosure Program"). During the term of the CIA, Cephalon shall maintain a Disclosure Program that includes a mechanism (a toll-free compliance telephone line) to enable individuals to disclose, to the Compliance Officer or some other person who is not in the disclosing individual's chain of command, any identified issues or questions associated with Cephalon's policies, conduct, practices, or procedures with respect to a Federal health care program or FDA requirement believed by the individual to be a potential violation of criminal, civil, or administrative law. Cephalon shall continue to appropriately publicize the existence of the disclosure mechanism (e.g., via periodic e-mails to employees or by posting the information in prominent common areas).

The Disclosure Program shall emphasize a nonretaliation policy, and shall include a reporting mechanism for anonymous communications for which appropriate confidentiality shall be maintained. Disclosures made by individuals residing outside the United States shall be in accordance with applicable laws, including the European Union Data Protection Directive. Upon receipt of a disclosure, the Compliance Officer (or designee) shall gather all relevant information from the disclosing individual. The Compliance Officer (or designee) shall make a preliminary, good faith inquiry into the allegations set forth in every disclosure to ensure that he or she has obtained all of the information necessary to determine whether a further review should be conducted. For any disclosure that is sufficiently specific so that it reasonably: (1) permits a determination of the appropriateness of the alleged improper practice; and (2) provides an opportunity for taking corrective action, Cephalon shall conduct an internal review of the allegations set forth in the disclosure and ensure that proper follow-up is conducted.

The Compliance Officer (or designee) shall maintain a disclosure log, which shall include a record and summary of each disclosure received (whether anonymous or not),

the status of the respective internal reviews, and any corrective action taken in response to the internal reviews. The disclosure log shall be made available to OIG upon request.

F. Ineligible Persons.

1. *Definitions.* For purposes of this CIA:

- a. an "Ineligible Person" shall include an individual or entity who:
 - i. is currently excluded, debarred, suspended, or otherwise ineligible to participate in the Federal health care programs or in Federal procurement or nonprocurement programs; or
 - ii. has been convicted of a criminal offense that falls within the ambit of 42 U.S.C. § 1320a-7(a), but has not yet been excluded, debarred, suspended, or otherwise declared ineligible.
- b. "Exclusion Lists" include:
 - i. the HHS/OIG List of Excluded Individuals/Entities (available through the Internet at <http://www.oig.hhs.gov>); and
 - ii. the General Services Administration's List of Parties Excluded from Federal Programs (available through the Internet at <http://www.epls.gov>).
- c. "Screened Persons" include: prospective and current owners of Cephalon (other than shareholders who: (1) have an ownership interest of less than 5%; and (2) acquired the ownership interest through public trading); and prospective and current officers, directors, employees, and contractors and agents of Cephalon. For purposes of employees residing outside the United States, "Screened Persons" shall be limited to Covered Persons.

2. *Screening Requirements.* Cephalon shall ensure that all Screened Persons are not Ineligible Persons, by implementing the following screening requirements.

- a. Cephalon shall screen all Screened Persons against the Exclusion Lists prior to engaging their services and, as part of the hiring or contracting process, shall require such Screened Persons to disclose whether they are Ineligible Persons.
- b. Cephalon shall screen all Screened Persons against the Exclusion Lists within 90 days after the Effective Date and on an annual basis thereafter.
- c. Cephalon shall implement a policy requiring all Screened Persons to disclose immediately any debarment, exclusion, suspension, or other event that makes that person an Ineligible Person.

Nothing in this Section affects the responsibility of (or liability for) Cephalon to refrain (if applicable) from billing Federal health care programs for items or services furnished, ordered, or prescribed by an Ineligible Person. Cephalon understands that items or services furnished by excluded persons are not payable by Federal health care programs and that Cephalon may be liable for overpayments (if applicable) and/or criminal, civil, and administrative sanctions for employing or contracting with an excluded person regardless of whether Cephalon meets the requirements of Section III.F.

3. *Removal Requirement.* If Cephalon has actual notice that a Screened Person has become an Ineligible Person, Cephalon shall remove such Screened Person from responsibility for, or involvement with, Cephalon's business operations related to the Federal health care programs and shall remove such Screened Person from any position for which the Screened Person's compensation or the items or services furnished, ordered, or prescribed by the Screened Person are paid in whole or part, directly or indirectly, by Federal health care programs or otherwise with Federal funds at least until such time as the Screened Person is reinstated into participation in the Federal health care programs.

4. *Pending Charges and Proposed Exclusions.* If Cephalon has actual notice that a Screened Person is charged with a criminal offense that falls within the

ambit of 42 U.S.C. §§ 1320a-7(a), 1320a-7(b)(1)-(3), or is proposed for exclusion during the Screened Person's employment or contract term, Cephalon shall take all appropriate actions to ensure that the responsibilities of that Screened Person have not and shall not adversely affect the accuracy of any claims submitted to any Federal health care program.

G. Notification of Government Investigation or Legal Proceedings.

Within 30 days after discovery by senior management at U.S. corporate headquarters, Cephalon shall notify OIG, in writing, of any ongoing investigation or legal proceeding known to Cephalon conducted or brought by a governmental entity or its agents involving an allegation that Cephalon has committed a crime or has engaged in fraudulent activities.

This notification shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding. Cephalon shall also provide written notice to OIG within 30 days after the resolution of the matter, and shall provide OIG with a description of the findings and/or results of the investigation or proceedings, if any.

H. Reporting.

1. *Reportable Events.*

a. *Definition of Reportable Event.* For purposes of this CIA, a "Reportable Event" means anything that involves:

i. a matter that a reasonable person would consider a probable violation of criminal, civil, or administrative laws applicable to any Federal health care program and/or applicable to any FDA requirements relating to the promotion of Cephalon products for which penalties or exclusion may be authorized; or

ii. the filing of a bankruptcy petition by Cephalon.

A Reportable Event may be the result of an isolated event or a series of occurrences.

b. *Reporting of Reportable Events.* If Cephalon determines (after a reasonable opportunity to conduct an appropriate review or investigation of the allegations) through any means that there is a Reportable Event, Cephalon shall notify OIG, in writing, within 30 days after making the determination that the Reportable Event exists. The report to OIG shall include the following information:

- i. a complete description of the Reportable Event, including the relevant facts, persons involved, and legal and Federal health care program and/or FDA authorities implicated;
- ii. a description of Cephalon's actions taken to correct the Reportable Event; and
- iii. any further steps Cephalon plans to take to address the Reportable Event and prevent it from recurring.
- iv. If the Reportable Event involves the filing of a bankruptcy petition, the report to the OIG shall include documentation of the filing and a description of any Federal health care program authorities and/or FDA authorities implicated.
- v. Cephalon shall not be required to report as a Reportable Event any matter previously disclosed under Section III.G above.

I. Notification of Communications with FDA.

Within 30 days after the date of any written report, correspondence, or communication between Cephalon and the FDA that materially discusses Cephalon's or a Covered Person's actual or potential unlawful or improper promotion of Cephalon's products (including any improper dissemination of information about off-label indications), Cephalon shall provide a copy of the report, correspondence, or communication to the OIG. Cephalon shall also provide written notice to the OIG within 30 days after the resolution of any such disclosed off-label matter, and shall provide the OIG with a description of the findings and/or results of the matter, if any.

J. Review of Records Reflecting the Content of Detailing Sessions.

Cephalon shall implement a Message Recall Monitoring Program designed to identify, for each Reporting Period, potential-off-label promotional activities by Cephalon's field sales force through the analysis of studies generated by an independent entity (Survey Entity) reflecting physician recall of the marketing messages delivered by Cephalon's sales force (Message Recall Studies) for up to three Covered Products (as defined below). Cephalon shall obtain Message Recall Studies for each Reporting Period. In order to satisfy its obligations under this Section III.J, Cephalon may propose that it obtain an alternative type of survey record (e.g. verbatims or similar records) rather than Message Recall Studies. The OIG will consider Cephalon's proposal, and after considering Cephalon's proposal shall, in its discretion, identify the type of survey records to be obtained.

For each Reporting Period and for each Covered Product, Cephalon shall contract with the Survey Entity to conduct Message Recall Studies. The OIG shall select and notify the Survey Entity of a one week period within every other quarter of the Reporting Period for which the Message Recall Studies shall be conducted beginning in the second full quarter after the Effective Date. For each Covered Product, Cephalon shall obtain Message Recall Studies covering the identified week in all regions across the United States.

Prior to the start of the second Reporting Period and every Reporting Period thereafter, based on the information provided and other information known to it, and after consultation with Cephalon, the OIG shall select up to three Government Reimbursed Products to be the basis for the review outlined in this Section III.J and shall notify Cephalon of its selection. These identified products shall be known as the "Covered Products." The parties have already identified the Covered Products for the first Reporting Period.

Cephalon shall review the records obtained from the Survey Entity and shall identify any instances in which the records appear to indicate that Covered Persons may have discussed and/or disseminated information about off-label uses of the Covered Products. Cephalon shall make findings based on its review (Off-Label Findings) and shall take any responsive action it deems necessary. If necessary for purposes of its review, Cephalon shall endeavor to gather additional factual information about the circumstances relating to any Off-Label Findings. As part of each Annual Report,

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Cephalon shall provide the OIG with copies of the underlying records of the detailing interactions, a copy of Cephalon's Off-Label Findings, and a description of the action(s), if any, Cephalon took in response to the Off-Label Findings.

K. Field Force Monitoring and Review Efforts.

To the extent not already accomplished, within 120 days after the Effective Date, Cephalon shall establish a Field Force Monitoring Program (FFMP) to evaluate and monitor field sales force representatives' interactions with HCPs. The FFMP shall be a formalized process designed to directly observe the appropriateness of field sales force representative's interactions with HCPs and to identify potential off-label promotional activities.

Under this program, Cephalon compliance personnel, or appropriately trained designees who are not from marketing or the field sales organizations and who are not within three levels of the field sales force representative's reporting structure, shall conduct direct field observations (Observations) of field sales force representatives to assess whether the messages delivered and materials distributed to HCPs are consistent with Cephalon's Policies and Procedures. These Observations shall be full day ride-alongs with field sales representatives, and each Observation shall consist of directly observing all meetings between a sales representative and HCPs during the workday. The Observations shall be scheduled throughout the year, randomly selected by Cephalon compliance personnel, include each therapeutic area and actively promoted product, and be conducted across the United States. At the completion of each Observation, Cephalon compliance personnel or the designee shall prepare a report which includes:

- 1) the identity of the sales representative;
- 2) the identity of the Cephalon compliance professional;
- 3) the date and duration of the Observation;
- 4) the product(s) promoted during the Observation;
- 5) an overall assessment of compliance with Cephalon policy; and
- 6) the identification of any potential off-label promotional activity by the field sales representative.

Cephalon compliance personnel shall conduct at least 30 full-day Observations during each Reporting Period. The number of inspections conducted for each therapeutic

area and product shall be proportional in number to the size of each therapeutic area and product, and shall be conducted across the United States.

In the event that a compliance issue, including potential off-label promotion, is identified during any Observation, Cephalon shall investigate the incident consistent with established Policies and Procedures for the handling of investigations. As part of the formal investigation procedures, findings shall be made and all necessary and appropriate responsive action (including disciplinary action) and corrective action shall be taken. The Compliance Officer shall disclose Reportable Events pursuant to Section III.H above, if applicable. Any compliance issues identified during an Observation and any corrective action shall be recorded in the files of Global Compliance.

Cephalon shall include a summary of the FFMP and the results of the FFMP as part of each Annual Report. As part of each Annual Report, Cephalon also shall provide the OIG with copies of the Observation report for any instances in which it was determined that improper promotion occurred and a description of the action(s) that Cephalon took as a result of such determinations. Cephalon shall make the Observation reports for all other Observations available to the OIG upon request.

L. Notice to Health Care Providers and Entities.

Within 90 days after the Effective Date, Cephalon shall send, by postage prepaid first class mail, Certificate of Mailing requested, an exact copy of the notice attached hereto as Attachment A, showing the date of the mailing, to any health care provider or entity that Cephalon currently details. This mailing shall notify each health care provider and entity of the terms of the global settlement with the United States, including an explanation of the conduct to which Cephalon pled guilty and the conduct resolved by the civil settlement. The mailing shall also notify each health care provider or entity that they may report any questionable conduct by Cephalon representatives to a compliance telephone number or e-mail address established by Cephalon or to the FDA.

The Chief Compliance Officer (or a designee) shall maintain a log of all calls and messages received by Cephalon in response to the notice. The log shall include a record and summary of each call and message received (whether anonymous or not), the status of the call or message, and any corrective action taken in response to the call or message. The disclosure log shall be made available to OIG upon request. As part of the

Implementation Report and each Annual Report, Cephalon shall provide to the OIG a summary of the calls and messages received.

M. Reporting of Physician Payments.

1. Phase I Reporting

By January 31, 2010, Cephalon shall post in a prominent position on its website an easily accessible and readily searchable listing of all physicians who received any Phase I Payments (as defined below in Section III.M.3) directly or indirectly from Cephalon during Calendar Year 2009 and the aggregate value of such payments in the calendar year.

After the initial posting, 30 days after the end of each subsequent calendar quarter until March 2011, Cephalon shall also post on its website a listing of updated information about all Phase I Payments provided during the applicable calendar year during the preceding quarter(s). The quarterly listing shall be easily accessible and readily searchable.

Each listing shall include a complete list of all individual physicians to whom Cephalon directly or indirectly made Phase I Payments in the preceding calendar year. Each listing shall be arranged alphabetically according to the physicians' last name. The Payment amounts in the lists shall be reported in \$10,000 increments (e.g., \$0 - \$10,000; \$10,001- \$20,000; etc.) For each physician, the applicable listing shall include the following information: i) full name; ii) city and state of the physician's practice; and iii) the aggregate value of the payment(s) in the preceding quarter(s) or year (as applicable). The reporting described in this Section III.M.1 shall be referred to hereafter as "Phase I Reporting."

2. Phase II Reporting

No later than March 31, 2011 and during the remaining term of the CIA, Cephalon shall post in a prominent position on its website an easily accessible and readily searchable listing of physicians and Related Entities (as defined in Section III.M.3) who received any Payments directly or indirectly from Cephalon and the aggregate value of such Payments in the preceding Calendar Year. After the initial posting, 30 days after the end of each subsequent calendar quarter Cephalon shall also post on its website a listing

of updated information about all Payments provided during the applicable calendar year during the preceding quarter(s). The quarterly listing shall be easily accessible and readily searchable.

Each listing shall include a complete list of all individual physicians and Related Entities to whom Cephalon directly or indirectly made Payments in the preceding calendar year. Each listing shall be arranged alphabetically according to the physicians' last name and the name of the Related Entity. The Payment amounts in the lists shall be reported in \$10,000 increments (*e.g.*, \$0 - \$10,000; \$10,001- \$20,000; *etc.*) For each physician and Related Entity, the applicable listing shall include the following information: i) full name; ii) city and state of the physician's practice; iii) name, city, and state in which the Related Entity is located; and iv) aggregate value of the Payment(s) in the preceding quarter(s) or year (as applicable). The reporting described in this Section III.M.2 shall be referred to hereafter as "Phase II Reporting."

3. Miscellaneous Provisions

Cephalon shall continue to make each annual listing and the most recent quarterly listing of both Phase I Reporting and Phase II Reporting available on its website at least throughout the term of this CIA. Cephalon shall retain and make available to OIG, upon request, all work papers, supporting documentation, correspondence, and records related to all applicable Payments and to the annual and quarterly listings of Payments. Nothing in this Section III.M affects the responsibility of Cephalon to comply with (or liability for noncompliance with) all applicable Federal health care program requirements and state laws as they relate to all applicable Payments made to physicians or Related Entities.

If the proposed Physician Payments Sunshine Act of 2008 or similar legislation is enacted, the OIG shall determine whether the purposes of this Section III.M are reasonably satisfied by Cephalon's compliance with such legislation. In such case, and in its sole discretion, the OIG may agree to modify or terminate provisions of Section III.M as appropriate.

For purposes of this Section III.M, the term "Payments" is defined to include all payments or transfers of value (whether in cash or in kind) made to physicians and/or to Related Entities. The term Payments includes, for example, payments or compensation for services rendered, grants, fees, honoraria, and payments relating to research or education. The term Payments also includes food, entertainment, gifts, trips or travel,

product(s)/item(s) provided for less than fair market value; or other economic benefit. The term Payments does not include: i) samples of drug products that meet the definition set forth in 21 C.F.R. § 203.3(i), or ii) discounts, rebates, or other pricing terms.

For purposes of this Section III.M, the term "Phase I Payments" is defined as those Payments made in connection with physicians serving as speakers, participating in speaker training, or serving as consultants (including for advisory boards, or preceptorships.)

For purposes of this Section III.M, the term "Related Entity" is defined to be any entity by or in which any physician receiving Payments is employed, has tenure, or has an ownership interest.

IV. CHANGES TO BUSINESS UNITS OR LOCATIONS

A. Change or Closure of Unit or Location. In the event that, after the Effective Date, Cephalon changes locations or closes a business unit or location related to Promotional and Product Services Related Functions, Cephalon shall notify OIG of this fact as soon as possible, but no later than within 30 days after the date of change or closure of the location.

B. Purchase or Establishment of New Unit or Location. In the event that, after the Effective Date, Cephalon purchases or establishes a new business unit or location related to Promotional and Product Services Related Functions, Cephalon shall notify OIG no later than the date the purchase or establishment is publicly disclosed. This notification shall include the address of the new business unit or location, phone number, fax number, Federal health care program provider or supplier number (if applicable), and the name and address of the contractor that issued each number (if applicable). Each new business unit or location and all Covered Persons at each new business unit or location shall be subject to the applicable requirements of this CIA.

C. Sale of Unit or Location. In the event that, after the Effective Date, Cephalon proposes to sell any or all of its business units or locations related to the Promotional and Product Services-Related Functions that are subject to this CIA, Cephalon shall notify OIG of the proposed sale no later than the date the sale is publicly disclosed. This notification shall include a description of the business unit or location to be sold, a brief

description of the terms of the sale, and the name and contact information of the prospective purchaser. This CIA shall be binding on the purchaser of such business unit or location, unless otherwise determined and agreed to in writing by the OIG.

V. IMPLEMENTATION AND ANNUAL REPORTS

A. **Implementation Report.** Within 150 days after the Effective Date, Cephalon shall submit a written report to OIG summarizing the status of its implementation of the requirements of this CIA (Implementation Report). The Implementation Report shall, at a minimum, include:

1. the name, address, phone number, and position description of the Chief Compliance Officer required by Section III.A.1, and a summary of other noncompliance job responsibilities the Compliance Officer may have;
2. the names and positions of the members of the Compliance Committee required by Section III.A.2;
3. (a) a copy of the letter (including all attachments) required by Sections II.C.6 and III.B.2 sent to each party employing Third Party Personnel; (b) a list of all such existing agreements; and (c) a description of the entities' response to Cephalon's letter;
4. the names and positions of the Certifying Employees required by Section III.A.4;
5. a copy of Cephalon's Code of Conduct required by Section III.B.1;
6. to the extent not already provided to the OIG, a copy of all Policies and Procedures required by Section III.B.3;
7. the number of individuals required to complete the Code of Conduct certification required by Section III.B.1, the percentage of individuals who have completed such certification, and an explanation of any exceptions (the documentation supporting this information shall be available to OIG, upon request);
8. the following information regarding each type of training required by Section III.C:

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- a. a description of such training, including a summary of the topics covered, the length of sessions, and a schedule of training sessions;
- b. the number of individuals required to be trained, percentage of individuals actually trained, and an explanation of any exceptions.

A copy of all training materials and the documentation supporting this information shall be available to OIG, upon request;

9. a description of the Disclosure Program required by Section III.E;
10. the following information regarding the IRO(s): (a) identity, address, and phone number; (b) a copy of the engagement letter; and (c) a summary and description of any and all current and prior engagements and agreements between Cephalon and the IRO;
11. a certification from the IRO regarding its professional independence and objectivity with respect to Cephalon;
12. a description of the process by which Cephalon fulfills the requirements of Section III.F regarding Ineligible Persons;
13. the name, title, and responsibilities of any person who is determined to be an Ineligible Person under Section III.F; the actions taken in response to the screening and removal obligations set forth in Section III.F;
14. a list of all of Cephalon's locations (including locations and mailing addresses); the corresponding name under which each location is doing business; the corresponding phone numbers and fax numbers; each location's Federal health care program provider or supplier number(s) (if applicable), and the name and address of each Federal health care program contractor to which Cephalon currently submits claims (if applicable);
15. a description of Cephalon's corporate structure, including identification of any parent and sister companies, subsidiaries, and their respective lines of business;

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16. a certification by the Chief Compliance Officer that the notice required by Section III.L was mailed to each health care provider and entity, the number of health care providers and entities that received a copy of the notice, a sample copy of the notice required by Section III.L, and a summary of the calls and messages received in response to the notice; and

17. the certifications required by Section V.C.

B. Annual Reports. Cephalon shall submit to OIG annually a report with respect to the status of, and findings regarding, Cephalon's compliance activities for each of the five Reporting Periods (Annual Report).

Each Annual Report shall include, at a minimum:

1. an explanation of any change in the identity, position description, or other noncompliance job responsibilities of the Chief Compliance Officer and any change in the membership of the Compliance Committee or Certifying Employees described in Sections III.A.1, 2 or 4;
2. a summary of any significant changes or amendments to the Policies and Procedures required by Section III.B.3 and the reasons for such changes (e.g., change in applicable requirements);
3. the number of individuals required to complete the Code of Conduct certification required by Section III.B.1, the percentage of individuals who have completed such certification, and an explanation of any exceptions (the documentation supporting this information shall be available to OIG, upon request);
4. (a) a copy of the letter (including all attachments) required by Sections II.C.6 and III.B.2 sent to each entity employing Third Party Personnel; (b) a list of all such existing agreements; and (c) a description of the entities' response to Cephalon's letter;
5. the following information regarding each type of training required by Section III.C:

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- a. a description of such training, including a summary of the topics covered, the length of sessions, and a schedule of training sessions;
- b. the number of individuals required to be trained, percentage of individuals actually trained, and an explanation of any exceptions.

A copy of all training materials and the documentation supporting this information shall be available to OIG, upon request.

6. a complete copy of all reports prepared pursuant to Section III.D, along with a copy of the IRO's engagement letter (if applicable);
7. Cephalon's response and corrective action plan(s) related to any issues raised by the reports prepared pursuant to Section III.D;
8. a summary and description of any and all current and prior engagements and agreements between Cephalon and the IRO, if different from what was submitted as part of the Implementation Report;
9. a certification from the IRO regarding its professional independence and objectivity with respect to Cephalon;
10. a summary of Reportable Events (as defined in Section III.H) identified during the Reporting Period and the status of any corrective and preventative action relating to all such Reportable Events;
11. a summary of the disclosures in the disclosure log required by Section III.E that relate to Federal health care programs;
12. any changes to the process by which Cephalon fulfills the requirements of Section III.F regarding Ineligible Persons;
13. the name, title, and responsibilities of any person who is determined to be an Ineligible Person under Section III.F; the actions taken by Cephalon in response to the screening and removal obligations set forth in Section III.F;

14. a summary describing any ongoing investigation or legal proceeding required to have been reported pursuant to Section III.G. The summary shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding;

15. a summary describing any communication with the FDA required to have been reported pursuant to Section III.I. This summary shall include a description of the matter and the status of the matter;

16. all information required by Section III.J;

17. all information required by Section III.K;

18. a summary of the calls and messages received in response to the notice required by Section III.L and the disposition of those calls and messages;

19. a description of all changes to the most recently provided list of Cephalon's locations (including addresses) as required by Section V.A.14; the corresponding name under which each location is doing business; the corresponding phone numbers and fax numbers; each location's Federal health care program provider or supplier number(s) (if applicable), and the name and address of each Federal health care program contractor to which Cephalon currently submits claims (if applicable);

20. a certification from the Chief Compliance Officer that information regarding payments has been posted on Cephalon's website as required Section III.M; and

21. the certifications required by Section V.C.

The first Annual Report shall be received by OIG no later than 60 days after the end of the first Reporting Period. Subsequent Annual Reports shall be received by OIG no later than the anniversary date of the due date of the first Annual Report.

C. Certifications. The following certifications shall be included in the Implementation Report and Annual Reports:

1. Certifying Employees: In each Annual Report, Cephalon shall include the certifications of Certifying Employees as required by Section III.A.4.

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2. Chief Compliance Officer: In each Implementation Report and Annual Report, Cephalon shall include the following individual certification by the Chief Compliance Officer:

a. he or she has reviewed the Report and has made reasonable inquiry regarding its content and believes that the information in the Report is accurate and truthful;

b. to the best of his or her knowledge, except as otherwise described in the applicable report, Cephalon is in compliance with Federal health care program and FDA requirements and the obligations of the CIA;

c. to the best of his or her knowledge, Cephalon has complied with its obligations under the Settlement Agreement: (a) not to resubmit to any Federal health care program payors any previously denied claims related to the Covered Conduct addressed in the Settlement Agreement, and not to appeal any such denials of claims; (b) not to charge to or otherwise seek payment from federal or state payors for unallowable costs (as defined in the Settlement Agreement); and (c) to identify and adjust any past charges or claims for unallowable costs;

d. Cephalon's: 1) Policies and Procedures as referenced in Section III.B.3 above; 2) templates for standardized contracts and other similar documents; and 3) the training materials used for purposes of Section III.C all have been reviewed by competent legal counsel and have been found to be in compliance with all applicable Federal health care program and FDA requirements. In addition, Cephalon's promotional materials containing claims or information about Government Reimbursed Products and other materials and information intended to be disseminated outside Cephalon have been reviewed by competent regulatory, medical and/or legal personnel in accordance with applicable Policies and Procedures to ensure that legal, medical, and regulatory concerns have been addressed and elevated when required, and that the materials and information when finally approved are in compliance with all applicable Federal health care program and FDA requirements. If the applicable legal requirements have not changed, after the initial review of the documents listed above, only material changes to the documents must be reviewed by competent regulatory, medical and/or legal personnel. The certification shall include a description of the document(s) reviewed and approximately when the

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review was completed. The documentation supporting this certification shall be available to OIG, upon request; and

e. Cephalon's call plans for Government Reimbursed Products were reviewed at least once during the Reporting Period (consistent with Section III.B.3.e) and, for each product the call plans were found to be consistent with Cephalon's policy objectives as referenced above in Section III.B.3.e.

D. Designation of Information. Cephalon shall clearly identify any portions of its submissions that it believes are trade secrets, or information that is commercial or financial and privileged or confidential, and therefore potentially exempt from disclosure under the Freedom of Information Act (FOIA), 5 U.S.C. § 552. Cephalon shall refrain from identifying any information as exempt from disclosure if that information does not meet the criteria for exemption from disclosure under FOIA.

VI. NOTIFICATIONS AND SUBMISSION OF REPORTS

Unless otherwise stated in writing after the Effective Date, all notifications and reports required under this CIA shall be submitted to the following entities:

OIG:

Administrative and Civil Remedies Branch
Office of Counsel to the Inspector General
Office of Inspector General
U.S. Department of Health and Human Services
Cohen Building, Room 5527
330 Independence Avenue, S.W.
Washington, DC 20201
Telephone: (202) 619-2078
Facsimile: (202) 205-0604

CEPHALON:

Executive Vice President, Chief Compliance Officer
Cephalon, Inc.
40 Moores Road
Frazer, PA 19355
Phone: (610) 727-6280
Facsimile: (610) 727-6001

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Unless otherwise specified, all notifications and reports required by this CIA may be made by certified mail, overnight mail, hand delivery, or other means, provided that there is proof that such notification was received. For purposes of this requirement, internal facsimile confirmation sheets do not constitute proof of receipt. Upon request by OIG, Cephalon may be required to provide OIG with an electronic copy of each notification or report required by this CIA in searchable portable document format (pdf), either instead of or in addition to, a paper copy.

VII. OIG INSPECTION, AUDIT, AND REVIEW RIGHTS

In addition to any other rights OIG may have by statute, regulation, or contract, OIG or its duly authorized representative(s) may examine or request copies of Cephalon's books, records, and other documents and supporting materials and/or conduct on-site reviews of any of Cephalon's locations for the purpose of verifying and evaluating: (a) Cephalon's compliance with the terms of this CIA; and (b) Cephalon's compliance with the requirements of the Federal health care programs in which it participates and with all applicable FDA requirements. The documentation described above shall be made available by Cephalon to OIG or its duly authorized representative(s) at all reasonable times for inspection, audit, or reproduction. Furthermore, for purposes of this provision, OIG or its duly authorized representative(s) may interview any of Cephalon's employees, contractors, or agents who consent to be interviewed at the individual's place of business during normal business hours or at such other place and time as may be mutually agreed upon between the individual and OIG. Cephalon shall assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. Cephalon's employees may elect to be interviewed with or without a representative of Cephalon present.

VIII. DOCUMENT AND RECORD RETENTION

Cephalon shall maintain for inspection all documents and records relating to reimbursement from the Federal health care programs, or to compliance with this CIA, for six years (or longer if otherwise required by law) from the Effective Date.

IX. DISCLOSURES

Consistent with HHS's FOIA procedures, set forth in 45 C.F.R. Part 5, OIG shall make a reasonable effort to notify Cephalon prior to any release by OIG of information submitted by Cephalon pursuant to its obligations under this CIA and identified upon submission by Cephalon as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, Cephalon shall have the rights set forth at 45 C.F.R. § 5.65(d).

X. BREACH AND DEFAULT PROVISIONS

Cephalon is expected to fully and timely comply with all of its CIA obligations.

A. Stipulated Penalties for Failure to Comply with Certain Obligations. As a contractual remedy, Cephalon and OIG hereby agree that failure to comply with certain obligations as set forth in this CIA may lead to the imposition of the following monetary penalties (hereinafter referred to as "Stipulated Penalties") in accordance with the following provisions.

1. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Cephalon fails to establish, implement, or accomplish any of the following obligations as described in Section III:

- a. a Compliance Officer;
- b. a Compliance Committee;
- c. the Board resolution;
- d. a written Code of Conduct;
- e. written Policies and Procedures;
- f. the training of Covered Persons;
- g. a Disclosure Program as required by Section III.E;

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- h. Ineligible Persons screening and removal requirements;
 - i. notification of Government investigations or legal proceedings;
 - j. notification of communications with FDA regarding off-label matters;
 - k. Message Recall Studies (or alternative information permitted by Section III.J);
 - l. a program for FFMP;
 - m. notification to any health care providers or entities as required by Section III.L; or
 - n. posting of any Payments as required by Section III.M.
2. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Cephalon fails to engage an IRO, as required in Section III.D and Appendices A-B.
3. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Cephalon fails to submit the Implementation Report or the Annual Reports to OIG in accordance with the requirements of Section V by the deadlines for submission.
4. A Stipulated Penalty of \$2,500 (which shall begin to accrue on the day after the date the obligation became due) for each day Cephalon fails to submit the annual IRO Review Report(s) in accordance with the requirements of Sections III.D and V.B.6 and Appendix B.
5. A Stipulated Penalty of \$1,500 for each day Cephalon fails to grant access as required in Section VII. (This Stipulated Penalty shall begin to accrue on the date Cephalon fails to grant access.)

6. A Stipulated Penalty of \$5,000 for each false certification submitted by or on behalf of Cephalon as part of its Implementation Report, Annual Report, additional documentation to a report (as requested by the OIG), or otherwise required by this CIA.

7. A Stipulated Penalty of \$1,000 for each day Cephalon fails to comply fully and adequately with any obligation of this CIA. OIG shall provide notice to Cephalon, stating the specific grounds for its determination that Cephalon has failed to comply fully and adequately with the CIA obligation(s) at issue and steps Cephalon shall take to comply with the CIA. (This Stipulated Penalty shall begin to accrue 10 days after Cephalon receives this notice from OIG of the failure to comply.) A Stipulated Penalty as described in this Subsection shall not be demanded for any violation for which OIG has sought a Stipulated Penalty under Subsections 1-6 of this Section.

B. Timely Written Requests for Extensions. Cephalon may, in advance of the due date, submit a timely written request for an extension of time to perform any act or file any notification or report required by this CIA. Notwithstanding any other provision in this Section, if OIG grants the timely written request with respect to an act, notification, or report, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until one day after Cephalon fails to meet the revised deadline set by OIG. Notwithstanding any other provision in this Section, if OIG denies such a timely written request, Stipulated Penalties for failure to perform the act or file the notification or report shall not begin to accrue until three business days after Cephalon receives OIG's written denial of such request or the original due date, whichever is later. A "timely written request" is defined as a request in writing received by OIG at least five business days prior to the date by which any act is due to be performed or any notification or report is due to be filed.

C. Payment of Stipulated Penalties.

1. *Demand Letter.* Upon a finding that Cephalon has failed to comply with any of the obligations described in Section X.A and after determining that Stipulated Penalties are appropriate, OIG shall notify Cephalon of: (a) Cephalon's failure to comply; and (b) OIG's exercise of its contractual right to demand payment of the Stipulated Penalties (this notification is referred to as the "Demand Letter").

2. *Response to Demand Letter.* Within 10 days after the receipt of the Demand Letter, Cephalon shall either: (a) cure the breach to OIG's satisfaction and pay

the applicable Stipulated Penalties; or (b) request a hearing before an HHS administrative law judge (ALJ) to dispute OIG's determination of noncompliance, pursuant to the agreed upon provisions set forth below in Section X.E. In the event Cephalon elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until Cephalon cures, to OIG's satisfaction, the alleged breach in dispute. Failure to respond to the Demand Letter in one of these two manners within the allowed time period shall be considered a material breach of this CIA and shall be grounds for exclusion under Section X.D.

3. *Form of Payment.* Payment of the Stipulated Penalties shall be made by electronic funds transfer to an account specified by the OIG in the Demand Letter.

4. *Independence from Material Breach Determination.* Except as set forth in Section X.D.1.c, these provisions for payment of Stipulated Penalties shall not affect or otherwise set a standard for OIG's decision that Cephalon has materially breached this CIA, which decision shall be made at OIG's discretion and shall be governed by the provisions in Section X.D, below.

D. Exclusion for Material Breach of this CIA.

1. *Definition of Material Breach.* A material breach of this CIA means:

- a. a failure by Cephalon to report a Reportable Event and take corrective action, as required in Section III.H;
- b. a repeated or flagrant violation of the obligations under this CIA, including, but not limited to, the obligations addressed in Section X.A;
- c. a failure to respond to a Demand Letter concerning the payment of Stipulated Penalties in accordance with Section X.C;
- d. a failure to engage and use an IRO in accordance with Section III.D; or
- e. a failure of the Board to issue a resolution in accordance with Section III.A.3.

2. *Notice of Material Breach and Intent to Exclude.* The parties agree that a material breach of this CIA by Cephalon constitutes an independent basis for Cephalon's exclusion from participation in the Federal health care programs. Upon a determination by OIG that Cephalon has materially breached this CIA and that exclusion is the appropriate remedy, OIG shall notify Cephalon of: (a) Cephalon's material breach; and (b) OIG's intent to exercise its contractual right to impose exclusion (this notification is hereinafter referred to as the "Notice of Material Breach and Intent to Exclude").

3. *Opportunity to Cure.* Cephalon shall have 30 days from the date of receipt of the Notice of Material Breach and Intent to Exclude to demonstrate to OIG's satisfaction that:

- a. Cephalon is in compliance with the obligations of the CIA cited by OIG as being the basis for the material breach;
- b. the alleged material breach has been cured; or
- c. the alleged material breach cannot be cured within the 30-day period, but that: (i) Cephalon has begun to take action to cure the material breach; (ii) Cephalon is pursuing such action with due diligence; and (iii) Cephalon has provided to OIG a reasonable timetable for curing the material breach.

4. *Exclusion Letter.* If, at the conclusion of the 30-day period, Cephalon fails to satisfy the requirements of Section X.D.3, OIG may exclude Cephalon from participation in the Federal health care programs. OIG shall notify Cephalon in writing of its determination to exclude Cephalon (this letter shall be referred to hereinafter as the "Exclusion Letter"). Subject to the Dispute Resolution provisions in Section X.E, below, the exclusion shall go into effect 30 days after the date of Cephalon's receipt of the Exclusion Letter. The exclusion shall have national effect and shall also apply to all other Federal procurement and nonprocurement programs. Reinstatement to program participation is not automatic. After the end of the period of exclusion, Cephalon may apply for reinstatement by submitting a written request for reinstatement in accordance with the provisions at 42 C.F.R. §§ 1001.3001-.3004.

E. Dispute Resolution.

1. *Review Rights.* Upon OIG's delivery to Cephalon of its Demand Letter or of its Exclusion Letter, and as an agreed-upon contractual remedy for the resolution of disputes arising under this CIA, Cephalon shall be afforded certain review rights comparable to the ones that are provided in 42 U.S.C. § 1320a-7(f) and 42 C.F.R. Part 1005 as if they applied to the Stipulated Penalties or exclusion sought pursuant to this CIA. Specifically, OIG's determination to demand payment of Stipulated Penalties or to seek exclusion shall be subject to review by an HHS ALJ and, in the event of an appeal, the HHS Departmental Appeals Board (DAB), in a manner consistent with the provisions in 42 C.F.R. § 1005.2-1005.21. Notwithstanding the language in 42 C.F.R. § 1005.2(c), the request for a hearing involving Stipulated Penalties shall be made within 10 days after receipt of the Demand Letter and the request for a hearing involving exclusion shall be made within 25 days after receipt of the Exclusion Letter.

2. *Stipulated Penalties Review.* Notwithstanding any provision of Title 42 of the United States Code or Title 42 of the Code of Federal Regulations, the only issues in a proceeding for Stipulated Penalties under this CIA shall be: (a) whether Cephalon was in full and timely compliance with the obligations of this CIA for which OIG demands payment; and (b) the period of noncompliance. Cephalon shall have the burden of proving its full and timely compliance and the steps taken to cure the noncompliance, if any. OIG shall not have the right to appeal to the DAB an adverse ALJ decision related to Stipulated Penalties. If the ALJ agrees with OIG with regard to a finding of a breach of this CIA and orders Cephalon to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless Cephalon requests review of the ALJ decision by the DAB. If the ALJ decision is properly appealed to the DAB and the DAB upholds the determination of OIG, the Stipulated Penalties shall become due and payable 20 days after the DAB issues its decision.

3. *Exclusion Review.* Notwithstanding any provision of Title 42 of the United States Code or Title 42 of the Code of Federal Regulations, the only issues in a proceeding for exclusion based on a material breach of this CIA shall be:

- a. whether Cephalon was in material breach of this CIA;

b. whether such breach was continuing on the date of the Exclusion Letter; and

c. whether the alleged material breach could not have been cured within the 30-day period, but that: (i) Cephalon had begun to take action to cure the material breach within that period; (ii) Cephalon has pursued and is pursuing such action with due diligence; and (iii) Cephalon provided to OIG within that period a reasonable timetable for curing the material breach and Cephalon has followed the timetable.

For purposes of the exclusion herein, exclusion shall take effect only after an ALJ decision favorable to OIG, or, if the ALJ rules for Cephalon, only after a DAB decision in favor of OIG. Cephalon's election of its contractual right to appeal to the DAB shall not abrogate OIG's authority to exclude Cephalon upon the issuance of an ALJ's decision in favor of OIG. If the ALJ sustains the determination of OIG and determines that exclusion is authorized, such exclusion shall take effect 20 days after the ALJ issues such a decision, notwithstanding that Cephalon may request review of the ALJ decision by the DAB. If the DAB finds in favor of OIG after an ALJ decision adverse to OIG, the exclusion shall take effect 20 days after the DAB decision. Cephalon shall waive its right to any notice of such an exclusion if a decision upholding the exclusion is rendered by the ALJ or DAB. If the DAB finds in favor of Cephalon, Cephalon shall be reinstated effective on the date of the original exclusion.

4. *Finality of Decision.* The review by an ALJ or DAB provided for above shall not be considered to be an appeal right arising under any statutes or regulations. Consequently, the parties to this CIA agree that the DAB's decision (or the ALJ's decision if not appealed) shall be considered final for all purposes under this CIA.

XI. EFFECTIVE AND BINDING AGREEMENT

Cephalon and OIG agree as follows:

A. This CIA shall be binding on the successors, assigns, and transferees of Cephalon;


B. This CIA shall become final and binding on the date the final signature is obtained on the CIA;

C. This CIA constitutes the complete agreement between the parties and may not be amended except by written consent of the parties to this CIA;

D. The undersigned Cephalon signatories represent and warrant that they are authorized to execute this CIA. The undersigned OIG signatory represents that he is signing this CIA in his official capacity and that he is authorized to execute this CIA; and

E. This CIA may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same CIA. Facsimiles of signatures shall constitute acceptable, binding signatures for purposes of this CIA.


ON BEHALF OF CEPHALON, INC.


Vitti Baldassano
Cephalon Chief Compliance Officer

9/29/08
Date


Gerald I. Pappert
Cephalon General Counsel

9/29/08
Date


Eric W. Sitarchuk
Counsel for Cephalon, Inc.

9/29/08
Date


Megan L. Traversari
Counsel for Cephalon, Inc.

9/29/08
Date

Corporate Integrity Agreement
Cephalon, Inc.

**ON BEHALF OF THE OFFICE OF INSPECTOR GENERAL
OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES**



Gregory E. Demske
Assistant Inspector General for Legal Affairs
Office of Inspector General
U. S. Department of Health and Human Services

9/26/08

Date

Corporate Integrity Agreement
Cephalon, Inc.

Attachment A

Dear Healthcare Provider:

As you may be aware Cephalon, Inc. recently entered into a global civil, criminal, and administrative settlement with the United States and individual states in connection with its promotion of three Cephalon products. This letter provides you with additional information about the settlement, explains Cephalon's commitments going forward, and provides you with access to information about those commitments. In general terms, the Government alleged that Cephalon unlawfully promoted three drugs (Actiq, Gabitril, and Provigil) for uses not approved by the Food & Drug Administration (FDA). To resolve these matters, Cephalon pled guilty to a misdemeanor criminal violation and agreed to pay a total of \$425 million to the Federal Government and state Medicaid programs. In addition, Cephalon paid \$6,150,000 in a companion settlement with the Connecticut Attorney General related to unfair trade practice laws. Additional information about the settlements may be found at the following websites [include a link to the USAO, Cephalon (www.cephalon.com), and Attorney General of Connecticut's websites.]

As part of the federal settlement, Cephalon also entered a five-year corporate integrity agreement with the Office of Inspector General of the U.S. Department of Health and Human Services. The corporate integrity agreement is available at <http://oig.hhs.gov/fraud/cia/index.html>. Under this agreement, Cephalon agreed to undertake certain obligations designed to promote compliance with Federal health care program and FDA requirements. We also agreed to notify healthcare providers about the settlement and inform them that they can report any questionable practices by Cephalon's representatives to Cephalon's Compliance Department or the FDA.

Please call or email Cephalon at 1-866-900-7167 or questions@cephalon.com if you have questions about the settlement referenced above or to report any instances in which you believe that a Cephalon representative inappropriately promoted a product or engaged in other questionable conduct. Alternatively, you may report any such instances to the FDA's Division of Drug Marketing, Advertising, and Communications at 301-796-1200. You should direct medical questions or concerns about the products to Cephalon's Medical Information department.

We appreciate your time and attention. We are dedicated to ensuring that we bring you the scientific and medical information you need to make well-informed decisions about whether Cephalon products are right for your patients.

Sincerely,

Chief Executive Officer
Cephalon, Inc.

APPENDIX A

INDEPENDENT REVIEW ORGANIZATION

This Appendix contains the requirements relating to the Independent Review Organization (IRO) required by Section III.D of the CIA.

A. IRO Engagement.

Cephalon shall engage an IRO that possesses the qualifications set forth in Paragraph B, below, to perform the responsibilities in Paragraph C, below. The IRO shall conduct the review in a professionally independent and objective fashion, as set forth in Paragraph D. Within 30 days after OIG receives written notice of the identity of the selected IRO, OIG will notify Cephalon if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Cephalon may continue to engage the IRO.

If Cephalon engages a new IRO during the term of the CIA, this IRO shall also meet the requirements of this Appendix. If a new IRO is engaged, Cephalon shall submit the information identified in Section V.A.10 of the CIA to OIG within 30 days of engagement of the IRO. Within 30 days after OIG receives written notice of the identity of the selected IRO, OIG will notify Cephalon if the IRO is unacceptable. Absent notification from OIG that the IRO is unacceptable, Cephalon may continue to engage the IRO.

B. IRO Qualifications.

The IRO shall:

1. assign individuals to conduct the Promotional and Product Services Review who have expertise in all applicable Federal health care program and FDA requirements relating to Promotional and Product Services Related Functions. The assigned individuals shall also be knowledgeable about the general requirements of the Federal health care program(s) under which Cephalon products are reimbursed;
2. assign individuals to design and select the samples for the Transaction Reviews who are knowledgeable about appropriate statistical sampling techniques; and
3. have sufficient staff and resources to conduct the reviews required by the CIA on a timely basis.

C. IRO Responsibilities.

The IRO shall:

1. perform each Promotional and Product Services Review in accordance with the specific requirements of the CIA;
2. follow all applicable Federal health care program and FDA requirements in making assessments in each Promotional and Product Services Review;
3. if in doubt of the application of a particular Federal health care program or FDA requirement, policy, or regulation, request clarification from the appropriate authority (e.g., CMS or FDA);
4. respond to all OIG inquiries in a prompt, objective, and factual manner; and
5. prepare timely, clear, well-written reports that include all the information required by Appendix B to the CIA.

D. IRO Independence and Objectivity.

The IRO must perform each Promotional and Product Services Review in a professionally independent and objective fashion, as appropriate to the nature of the engagement, taking into account any other business relationships or engagements that may exist between the IRO and Cephalon.

E. IRO Removal/Termination.

1. *Provider.* If Cephalon terminates its IRO during the course of the engagement, Cephalon must submit a notice explaining its reasons to OIG no later than 30 days after termination. Cephalon must engage a new IRO in accordance with Paragraph A of this Appendix.

2. *OIG Removal of IRO.* In the event OIG has reason to believe that the IRO does not possess the qualifications described in Paragraph B, is not independent and/or objective as set forth in Paragraph D, or has failed to carry out its responsibilities as described in Paragraph C, OIG may, at its sole discretion, require Cephalon to engage a new IRO in accordance with Paragraph A of this Appendix.

Prior to requiring Cephalon to engage a new IRO, OIG shall notify Cephalon of its intent to do so and provide a written explanation of why OIG believes such a step is necessary. To resolve any concerns raised by OIG, Cephalon may request a meeting with OIG to discuss any aspect of the IRO's qualifications, independence or performance of its

responsibilities and to present additional information regarding these matters. Cephalon shall provide any additional information as may be requested by OIG under this Paragraph in an expedited manner. OIG will attempt in good faith to resolve any differences regarding the IRO with Cephalon prior to requiring Cephalon to terminate the IRO. However, the final determination as to whether or not to require Cephalon to engage a new IRO shall be made at the sole discretion of OIG.

**Appendix B to CIA for Cephalon, Inc.
Promotional and Product Services Review**

I. Promotional and Product Services Review, General Description

As specified more fully below, Cephalon shall retain an Independent Review Organization (IRO) to perform reviews to assist Cephalon in assessing and evaluating its systems, processes, policies, procedures, and practices related to Cephalon's Promotional and Product Services Related Functions (Promotional and Product Services Review). The Promotional and Product Services Review shall consist of two components - a systems review (the "Promotional and Product Services Systems Review" or "Systems Review"), and a transactions review (the "Promotional and Product Services Transactions Review" or "Transactions Review") as described more fully below. Cephalon may engage, at its discretion, a single IRO to perform both components of the Promotional and Product Services Review provided that the entity has the necessary expertise and capabilities to perform both.

If there are no material changes in Cephalon's systems, processes, policies, and procedures relating to Promotional and Product Services Related Functions, the IRO shall perform the Promotional and Product Services Systems Review for the first and fourth Reporting Periods. If Cephalon materially changes its systems, processes, policies, and procedures relating to Promotional and Product Services Related Functions, the IRO shall perform a Promotional and Product Services Systems Review for the Reporting Period(s) in which such changes were made in addition to conducting the Review for the first and fourth Reporting Periods. The additional Systems Review(s) shall consist of: 1) an identification of the material changes; 2) an assessment of whether other systems, processes, policies, and procedures previously reported did not materially change; and 3) a review of the systems, processes, policies, and procedures that materially changed. The IRO shall conduct the Promotional and Product Services Transactions Review for each Reporting Period of the CIA.

II. Promotional and Product Services Systems Review

A. Description of Reviewed Policies and Procedures

The Promotional and Product Services Systems Review shall be a review of Cephalon's systems, processes, policies, and procedures (including the controls on those systems, processes, policies, and procedures) relating to certain Promotional and Product Services Related Functions. Where practical, Cephalon personnel may compile documentation, schedule and organize interviews, and undertake other efforts to assist the IRO in performing the Systems Review. The IRO is not

required to undertake a de novo review of the information gathered or activities undertaken by Cephalon pursuant to the preceding sentence.

Specifically, the IRO shall review Cephalon's systems, processes, policies, and procedures associated with the following (hereafter "Reviewed Policies and Procedures"):

1) Cephalon's systems, policies, processes, and procedures applicable to the manner in which Cephalon representatives (including sales representatives and/or Medical Services department personnel) handle requests or inquiries relating to information about the uses of Cephalon products (including non-FDA-approved (*i.e.*, off-label) uses) and the dissemination of materials relating to off-label uses of products. This review includes:

- a) the manner in which Cephalon sales representatives and marketing personnel handle requests for information about off-label uses of Cephalon products (*i.e.*, by referring all such requests to Medical Services department personnel at Cephalon);
- b) the manner in which Medical Services department personnel, including those at Cephalon's headquarters, handle and respond to requests for information about off-label uses of Cephalon products (including tracking the requests and using pre-approved materials for purposes of responding to the request);
- c) the form and content of information and materials related to Cephalon's products disseminated to physicians, pharmacists, or other health care professionals (collectively "HCPs") or health care institutions (HCIs) by Cephalon;
- d) Cephalon's systems, processes, and procedures (including the Inquiries Database) to track requests for information about off-label uses of products and responses to those requests;
- e) the manner in which Cephalon collects and supports information reported in any systems used to track and respond to requests for product information, including its Inquiries Database;
- f) the processes and procedures by which the Compliance Officer (and other appropriate individuals within Cephalon) identify situations in which it appears that improper off-label promotion may have occurred; and

- g) Cephalon's processes and procedures for investigating, documenting, resolving, and taking appropriate disciplinary action for potential situations involving off-label promotion;
- 2) Cephalon's policies and procedures applicable to the manner and circumstances under which its Medical Services department personnel (including any medical science liaisons (MSLs)) participate in meetings or events with HCPs or HCIs (either alone or with sales representatives) and the role of the medical personnel at such meetings or events;
- 3) Cephalon's systems, policies, processes, and procedures relating to Cephalon's internal review and approval of information and materials related to Cephalon's products disseminated to HCPs or HCIs by Cephalon;
- 4) Cephalon's systems, policies, processes and procedures relating to incentive compensation for Covered Persons who are sales representatives, with regard to whether the systems, policies, processes, and procedures are designed to ensure that financial incentives do not inappropriately motivate such individuals to engage in the improper promotion, sales, and marketing of Cephalon's products. This shall include a review of the bases upon which compensation is determined and the extent to which compensation is based on product performance; and
- 5) Cephalon's systems, processes, policies, and procedures relating to the development and review of call plans for Cephalon's products. This shall include a review of the bases upon which HCPs and HCIs belonging to specified medical specialties are included in, or excluded from, the call plans based on expected utilization of Cephalon products for FDA-approved uses or non-FDA-approved uses.

B. Promotional and Product Services Systems Review Report

The IRO shall prepare a report based upon each Systems Review. For each of the Reviewed Policies and Procedures identified in Section II.A above, the report shall include the following items:

- 1) a description of the documentation (including policies) reviewed and any personnel interviewed;

- 2) a detailed description of Cephalon's systems, policies, processes, and procedures relating to the items identified in Sections II.A.1-5 above, including a general description of Cephalon's control and accountability systems (e.g., documentation and approval requirements, and tracking mechanisms) and written policies regarding the Reviewed Policies and Procedures;
- 3) a description of the manner in which the control and accountability systems and the written policies relating to the items identified in Sections II.A.1-5 above are made known or disseminated within Cephalon;
- 4) a detailed description of any system(s) used to track and respond to requests for information about Cephalon's products (including the Inquiries Database);
- 5) a detailed description of Cephalon's incentive compensation system for Covered Persons who are sales representatives, including a description of the bases upon which compensation is determined and the extent to which compensation is based on product performance. To the extent that Cephalon may establish compensation differently for individual products, the IRO shall report separately on each such type of compensation arrangement;
- 6) findings and supporting rationale regarding any weaknesses in Cephalon's systems, processes, policies, and procedures relating to the Reviewed Policies and Procedures, if any; and
- 7) recommendations to improve any of the systems, policies, processes, or procedures relating to the Reviewed Policies and Procedures, if any.

III. Promotional and Product Services Transaction Review

As described more fully below in Sections III.A-D, the Promotional and Product Services Transactions Review shall include: (1) a review of a sample of Inquiries reflected in the Inquiries Database; (2) a review of Cephalon's call plans and Cephalon's call plan review process; (3) a review of records relating to a sample of the Payments that are reported by Cephalon pursuant to Section III.M of the CIA; and (4) a review of up to three additional items identified by the OIG in accordance with Section III.D.1.b of the CIA (hereafter "Additional Items".) The

IRO shall report on all aspects of its reviews in the Promotional and Product Services Transactions Review Reports.

A. Review of Inquiries and Inquiries Database

1) Description of Inquiries Database

As set forth in Section III.B.3.d of the CIA, Cephalon shall establish a database to track information relating to requests for information received by Cephalon about its products (hereafter "Inquiries"). Specifically, Cephalon shall document and record all Inquiries received from HCPs or HCIs regarding Cephalon's products in a database (the "Inquiries Database"). Cephalon shall record in the Inquiries Database the following information for each Inquiry received: 1) date of Inquiry; 2) form of Inquiry (e.g., fax, phone, medical information request form); 3) name of requesting HCP or HCI; 4) nature and topic of request (including exact language of the Inquiry if made in writing); 5) nature/form of the response from Cephalon (including a record of any materials provided in response to the request); and 6) the name of the Cephalon representative who called upon or interacted with the HCP or HCI. Any response from Medical Services to an HCP or HCI shall identify whether the information provided addresses an indication that is part of an approved product label. The status and findings of any follow-up review conducted by Cephalon in situations in which improper off-label promotion is suspected shall be maintained by Global Compliance.

2) Internal Review of Inquiries Database

On a semi-annual basis, the Compliance Officer or other appropriate personnel shall review the Inquiries Database and related information, as appropriate, and shall generate a report summarizing the items of information outlined in Section III.A.1 above for each Inquiry received during the preceding two quarters ("Inquiry Report"). The Compliance Officer or other appropriate personnel shall review the Inquiry Reports to assess whether the information contained in the report suggests that improper off-label promotion may have occurred in connection with any Inquiry(ies). If the Compliance Officer or other appropriate personnel, in consultation with other appropriate Cephalon personnel, suspects that improper off-label promotion may have occurred in connection with any Inquiry, the Compliance Officer or other appropriate personnel shall

undertake a follow-up review of the Inquiry (Off-Label Review), make specific findings based on his/her Off-Label Review, and take all appropriate responsive action (including disciplinary action of the Covered Person and reporting of the conduct, including disclosing Reportable Events pursuant to Section III.H of the CIA, if applicable).

3) IRO Review of Inquiries Reflected in Inquiries Database

The IRO shall select and review a random sample of 60 Inquiries from among the Inquiries reflected in the Inquiries Database for each Reporting Period. Forty-five of the Inquiries reviewed by the IRO shall be Inquiries for which Cephalon conducted an Off-Label Review, and the other 15 shall be Inquiries for which Cephalon did not conduct an Off-Label Review. For each Inquiry reviewed, the IRO shall determine:

- a) Whether each item of information listed above in Section III.A.1 is reflected in the Inquiries Database for each reviewed Inquiry; and
- b) For each Inquiry for which the Compliance Officer or other appropriate personnel conducted an Off-Label Review, the basis for suspecting that improper off-label promotion may have occurred; the steps undertaken as part of the Off-Label Review; the findings of the Compliance Officer or other appropriate personnel as a result of the Off-Label Review; and any follow-up actions taken by Cephalon based on the Off-Label Review findings.

B. IRO Review of Cephalon's Call Plans and Call Plan Review Process

The IRO shall conduct a review and assessment of Cephalon's review of its call plans for Government Reimbursed Products as set forth in Section III.B.3.e of the CIA. Cephalon shall provide the IRO with: i) a list of products promoted by Cephalon during the Reporting Period; ii) information about the FDA-approved uses for each Cephalon product; and iii) the call plans for each product. Cephalon shall also provide the IRO with information about the reviews of call plans that Cephalon conducted during the Reporting Period and any modifications to the call plans made as a result of Cephalon's reviews.

For each call plan, the IRO shall select a sample of 50 of the HCPs and HCIs included on the call plan. For each call plan, the IRO shall compare the

sampled HCPs and HCIs against the criteria (e.g., medical specialty or practice area) used by Cephalon in conducting its review and/or modification of the call plan in order to determine whether Cephalon followed its criteria and Policies and Procedures in reviewing and modifying the call plan.

The IRO shall note any instances in which it appears that the sampled HCPs and HCIs on a particular call plan are inconsistent with Cephalon's criteria relating to the call plan and/or Cephalon's Policies and Procedures. The IRO shall also note any instances in which it appears that Cephalon failed to follow its criteria or Policies and Procedures.

C. IRO Review of Physician Payment Listings

1. Information Contained in Physician Payment Listings

As set forth in Section III.M of the CIA, Cephalon shall post quarterly and annual listings of physicians and Related Entities who received Payments, as defined in the CIA, directly or indirectly from Cephalon. For purposes of the IRO review as set forth in this Section III.C, each annual listing shall be referred to as the "Physician Payment Listing" or "Listing." For each physician and Related Entity, each Physician Payment Listing shall include the following information: i) full name; ii) city and state of the physician; iii) name, city, and state of the Related Entity (if applicable); and iv) the aggregate value of the Payment(s) in the preceding year.

For purposes of this IRO review, the term "Control Documents" shall include all documents or electronic records associated with each Payment reflected in the Physician Payments Listing for the sampled physician and/or Related Entity. For example, the term "Control Documents" includes, but is not limited to, documents relating to the nature, purpose, and amount of all Payments reflected in the Listing; contracts relating to the Payment(s) reflected in the Listing; documents relating to the occurrence of Payment(s) reflected in the Listing; documents reflecting any work product generated in connection with the Payment(s); documents submitted by sales representatives or headquarters personnel to request approval for the Payment(s); and business rationale or justification forms relating to the Payment(s).

2. Selection of Sample for Review

For each Reporting Period, the OIG shall have the discretion to identify 50 physicians or Related Entities from the applicable Physician Payment Listing that will be subject to the IRO review described below. If the OIG elects to exercise this discretion, it shall notify the IRO of the 50 physicians and/or Related Entities

subject to the IRO review. If the OIG elects not to exercise its discretion as described above, the IRO shall randomly select 50 physicians and/or Related Entities to be included in the review. For each selected physician and/or Related Entity, the IRO shall review the entry in the Physician Payment Listing and the Control Documents relating to Payments reflected in Listing identified by the IRO as necessary and sufficient to validate the Payment information in the Listing.

3. IRO Review of Control Documents for Selected Physicians and/or Related Entities

For each physician and/or Related Entity selected as part of the sample, the IRO shall review the Control Documents identified by the IRO as necessary and sufficient to validate each Payment reflected in the Listing to evaluate the following:

- a) Whether Control Documents are available relating to each Payment reflected in the Listing for the sampled physician and/or Related Entity;
- b) Whether the Control Documents were completed and archived in accordance with the requirements set forth in Cephalon's policies;
- c) Whether the aggregate value of the Payment(s) as reflected in the Listing for the sampled Physician is consistent with the value of the Payments(s) reflected in the Control Documents; and
- d) Whether the Control Documents reflect that Cephalon's policies were followed in connection with Payment(s) reflected in the Listing (e.g., all required written approvals for the activity were obtained in accordance with Cephalon's policies.)

4. Identification of Material Errors and Additional Review

A Material Error is defined as any of the following:

- a) A situation in which all required Control Documents relating to Payments reflected in the Listing for the sampled physician and/or Related Entity do not exist and:

- i. no corrective action was initiated prior to the selection of the sampled physicians and/or Related Entities; or
 - ii. the IRO cannot confirm that Cephalon otherwise followed its policies and procedures relating to the entry in the Listing for the sampled physician or Related Entity, including its policies and procedures relating to any Payment(s) reflected in the Listing; or
- b) Information or data is omitted from key fields in the Control Documents that prevents the IRO from assessing compliance with Cephalon's policies and procedures, and the IRO cannot obtain this information or data from reviewing other Control Documents.

If a Control Document does not exist, but Cephalon has initiated corrective action prior to the selection of the sampled physicians and/or Related Entities, or if a Control Document does not exist but the IRO can determine that Cephalon otherwise followed its policies and procedures with regard to each entry in the Listing for a sampled physician or Related Entity, the IRO shall consider such a situation to be an exception (rather than a Material Error) and the IRO shall report the situation as such. Similarly, the IRO shall note as exceptions any Control Documents for which non-material information or data is omitted.

If the IRO identifies any Material Errors, the IRO shall conduct such Additional Review of the underlying Payment associated with the erroneous Control Documents as may be necessary to determine the root cause of the Material Errors. For example, the IRO may need to review additional documentation and/or conduct interviews with appropriate personnel to identify the root cause of the Material Error(s) discovered.

D. IRO Review of Additional Items

As set forth in Section III.D.1.b of the CIA and beginning with the second Reporting Period, the OIG at its discretion may identify up to three additional items for the IRO to review (hereafter "Additional Items".) No later than 90 days prior to the end of the second through fifth Reporting Periods, the OIG shall notify Cephalon of the nature and scope of the IRO review to be conducted for each of the Additional Items. Prior to undertaking the review of the Additional Items, the IRO and/or Cephalon shall submit an audit work plan to the OIG for approval and the IRO shall conduct the review of the Additional Items based on a work plan approved by the OIG. The IRO shall include information about its review of each

Additional Item in the Transactions Review Report (including a description of the review conducted for each Additional Item; the IRO's findings based on its review for each Additional Item; and the IRO's recommendations for any changes in Cephalon's systems, processes, policies, and procedures based on its review of each Additional Item.)

Cephalon may propose to the OIG that its internal audit(s) be partially substituted for one or more of the Additional Items that would otherwise be reviewed by the IRO for the applicable Reporting Period. The OIG retains sole discretion over whether, and in what manner, to allow Cephalon's internal audit work to be substituted for a portion of the Additional Items review conducted by the IRO.

In making its decision, the OIG agrees to consider, among other factors, the nature and scope of Cephalon's planned internal audit work, the results of the Transactions Review(s) during prior Reporting Period(s), and Cephalon's demonstrated audit capabilities to perform the proposed audit work internally. If the OIG denies Cephalon's request to permit its internal audit work to be substituted for a portion of the IRO's review of Additional Items in a given Reporting Period, Cephalon shall engage the IRO to perform the Review as outlined in this Section III.

If the OIG agrees to permit certain of Cephalon's internal audit work for a given Reporting Period to be substituted for a portion of Additional Items review, such internal work would be subject to verification by the IRO (Verification Review). In such an instance, the OIG would provide additional details about the scope of the Verification Review to be conducted by the IRO. However, for purposes of any Verification Review, the IRO shall review of at least 20% of the sampling units reviewed by Cephalon in its internal audits.

E. Promotional and Product Services Transactions Review Report

For each Reporting Period, the IRO shall prepare a report based on its Promotional and Product Services Transactions Review. The report shall include the following:

- 1) General Elements to Be Included in Report
 - a) Review Objectives: A clear statement of the objectives intended to be achieved by each part of the review;
 - b) Review Protocol: A detailed narrative description of the procedures performed and a description of the sampling unit

and universe utilized in performing the procedures for each sample reviewed; and

- c) Sources of Data: A full description of documentation and other information, if applicable, relied upon by the IRO in performing the Promotional and Product Services Transactions Review.

2) Results to be Included in Report

The following results shall be included in each Promotional and Product Services Review Report:

(Relating to the Review of Inquiries)

- a) in connection with the review of Inquiries, a description of each type of sample unit reviewed, including the number of each type of sample units reviewed (e.g., the number of Inquiries) and an identification of the types of documents and information reviewed for the Inquiries;
- b) for each Inquiry sample unit, the IRO shall summarize the information about the Inquiry contained in the Inquiries Database;
- c) for each Inquiry sample unit, findings and supporting rationale as to whether: (i) each item of information listed in Section III.A.1 is reflected in the Inquiries Database; and (ii) for each Inquiry for which an Off-Label Review was conducted, the basis for suspecting that improper off-label promotion may have occurred; the steps undertaken as part of the Off-Label Review; the findings of the Compliance Officer as a result of the Off-Label Review; and any follow-up actions taken by Cephalon as a result of the Compliance Officer's findings;
- d) the findings and supporting rationale regarding any weaknesses in Cephalon's systems, processes, policies, procedures, and practices relating to the Inquiries, and the Inquiries Database, if any;

- e) recommendations for improvement in Cephalon's systems, processes, policies, procedures, and practices relating to the Inquiries and the Inquiries Database, if any;

(Relating to the Call Plan Reviews)

- f) a list of the products promoted by Cephalon during the Reporting Period and a summary of the FDA-approved uses for such products;
- g) for each Cephalon product: i) a description of the criteria used by Cephalon in developing or reviewing the call plans and for including or excluding specified types of HCPs or HCIs from the call plans; ii) a description of the review conducted by Cephalon of the call plans and an indication of whether Cephalon reviewed the call plans as required by Section III.B.3.e of the CIA; iii) a description of all instances for each call plan in which it appears that the HCPs and HCIs included on the call plan are inconsistent with Cephalon's criteria relating to the call plan and/or Cephalon's Policies and Procedures; and iv) a description of all instances in which it appears that Cephalon failed to follow its criteria or Policies and Procedures relating to call plans or the review of the call plans;
- h) the findings and supporting rationale regarding any weaknesses in Cephalon's systems, processes, policies, procedures, and practices relating to Cephalon's call plans or the review of the call plans, if any;
- i) recommendations, if any, for changes in Cephalon's systems, processes, policies, procedures, and practices that would correct or address any weaknesses or deficiencies uncovered during the Transactions Review with respect to call plans or the review of the call plans;

(Relating to the Physician Payment Listing Reviews)

- j) a description of the entries in the Physician Payment Listing for each physician or Related Entity sampled and a description of Control Documents reviewed in connection with each selected physician or Related Entity;

- k) for each sampled physician or Related Entity, findings and supporting rationale as to whether: (i) all required Control Documents exist; (ii) each Control Document was completed in accordance with all of the requirements set forth in the applicable Cephalon policy; (iii) the aggregate value of the Payment(s) as reflected in the Listing for the sampled physician or entity is consistent with the value of the Payment(s) reflected in the Control Documents; (iv) each Control Document reflects that Cephalon's policies were followed in connection with the underlying activity reflected in the document (e.g., all required approvals were obtained); and (v) any disciplinary action was undertaken in those instances in which Cephalon policies were not followed;
- l) for each sampled physician or Related Entity unit reviewed, an identification and description of all exceptions discovered. The report shall also describe those instances in which corrective action was initiated prior to the selection of the sampled physicians or Related Entities, including a description of the circumstances requiring corrective action and the nature of the corrective action;
- m) if any Material Errors are discovered in any sample unit reviewed, a description of the error, the Additional Review procedures performed and a statement of findings as to the root cause(s) of the Material Error;

(Relating to the Review of Additional Items)

- n) for each Additional Item reviewed, a description of the review conducted;
- o) for each Additional Item reviewed, the IRO's findings based on its review;
- p) for each Additional Item reviewed, the findings and supporting rationale regarding any weaknesses in Cephalon's systems, processes, policies, procedures, and practices relating to the Additional Item, if any; and
- q) for each Additional Item reviewed, recommendations, if any, for changes in Cephalon's systems, processes, policies, and

procedures that would correct or address any weaknesses or deficiencies uncovered during the review.